

REMARKS

In this Amendment, claims 20, 26-30, 32, and 33 are amended. After entry of this Amendment, claims 20-24, 26-30, 32, and 33 will be pending in the application.

Specifically, the claims have been amended as follows.

Independent claim 20 has been amended to even more clearly recite that protein sequences are predicted from “either” whole genomic sequences, or from partial genomic sequences comprising at least one chromosome. This amendment further clarifies the existing claim language.

Independent claim 20 has been amended to remove the limitation “displaying the results of said clustering.” The limitation was previously added on the basis of the Patent Office’s continued assertion that a physical transformation step, such as a “displaying step,” is required for a claim to define patentable subject matter under Section 101. However, this limitation is clearly unnecessary, as now recognized by the Patent Office at page 2 of the Office Action.

Step (d) of independent claim 20 is amended to recite the comparing step more particularly. Step (d) recites: “comparing said outlier proteins with protein databases to identify outlier proteins that are unique to said pathogenic organism, and to identify outlier proteins that are homologous or identical to proteins known to be involved in virulence.” This amendment is supported by the specification at page 7, lines 15-20, for example, describing that the outlier proteins may be “unique” to the pathogenic organism, or may be identical or homologous to other proteins involved in virulence.

Steps (e) and (f) of independent claim 20 have further been amended to correct for antecedent basis.

Claims 26-28 have been amended to correct for antecedent basis.

Claim 29 has been amended to recite that “steps (a)-(c) are performed by a computer system.” This amendment is supported by the original and existing claim language, which clearly indicate that the computer system performs the “calculating” and “clustering” steps; that is, the steps of the independent claim that recite “computationally.”

Claims 30, 32, and 33 have been amended to correct for antecedent basis, and to even more clearly define the “validating” step of the independent claim. These amendments are supported by the specification at page 7, lines 3-8.

No new matter has been added, and entry of this Amendment is requested.

I. Response to Claim Rejections Under 35 U.S.C. § 101

At page 2 of the Office Action, claims 20-24, 26-30, and 32-33 are rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter.

Specifically, the Examiner states that, under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published November 11, 2005), a method that does not result in a physical transformation of matter must produce a concrete, tangible and useful result (i.e. be directed to a practical application) to be patentable subject matter.

With respect to the present claims, the Examiner contends that the “validating” step of independent claim 20 is not necessarily a physical step, and thus the claim does not recite a

physical transformation of matter. The Examiner concludes that the claims do not produce a concrete, tangible and useful result, and thus they are directed to non-statutory subject matter.

This rejection is respectfully traversed.

Initially, it is acknowledged that the Examiner has re-instituted this rejection in view of the new examination guidelines published November 22, 2005. These examination guidelines clarify that, for computer-implemented methods, a physical transformation step is not necessary under Section 101 so long as the claimed method results in a concrete, tangible and useful result; that is, a practical application. (In fact, this interpretation of Section 101, which follows from well-established Federal Circuit case law, has been asserted by the Applicants during the course of prosecution. See, for example, the Amendments filed February 2, 2003, September 14, 2004, and February 18, 2005).

The requirement for a concrete, tangible, and useful result is to assure that the claimed method does not patent mathematical principles in the abstract, but only when connected to a practical application.

The Examiner, in concluding that the claimed method does not produce a concrete, tangible and useful result, provides no analysis or reasoning whatsoever. The Examiner does not indicate why the claimed method does not result in a concrete, tangible and useful result, nor does the Examiner indicate what, in the Examiner's opinion, such a result would be.

The claimed method ***results in the identification of diagnostic targets, drug targets, and vaccine candidates*** as is clear from the specification and dependent claims 30, 32 and 33. Such

is clearly a practical application. For example, the claims do not recite manipulation of sequence data for no particular reason, or with no useful result.

Further, there are numerous U.S. patents that claim methods of identifying drug targets or candidate drug compounds (such as vaccines), and thus, the Office Action is contrary to the established utility of countless U.S. patents.

The claims are very clearly directed to statutory subject matter, and thus withdrawal of this rejection is requested.

If the Examiner does not believe that the claimed method produces a concrete, tangible, and useful result, the Examiner is kindly requested to state why the Examiner believes that such is the case, in the interest of compact and efficient prosecution of the present application.

II. Response to Claim Rejections Under 35 U.S.C. §112, Second Paragraph

At page 3 of the Office Action, claims 20-24, 26-30, and 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the following reasons.

(1) The Examiner states that step (a) renders claim 20 indefinite, because it is allegedly unclear if whole genomic sequences also comprise at least one chromosome.

(2) The Examiner states that the relationship between step (d) and the rest of claim 20 renders this claim indefinite. Specifically, the Examiner asks whether the “outlier proteins” of step (d) are the same as those identified in step (c).

(3) The Examiner states that step (d) of claim 20 is further unclear as to the type of comparison being performed.

(4) The Examiner states that the limitation “an outlier protein” in step (e) renders claim 20 indefinite, because it is unclear to the Examiner whether the outlier protein of step (e) is the same as that recited in step (c) and/or (d).

The Examiner further states that the relationship between steps (d) and (e) is unclear, that is, it is unclear to the Examiner whether an outlier protein is selected in step (e) on the basis of the results in step (d).

(5) The Examiner states that the CPU element of claim 29 renders this claim indefinite, because it is unclear to the Examiner how these “steps” relate to the independent claim.

(6) The Examiner states that the language “using said outlier protein for a...purpose” renders claims 30 and 32 indefinite. Further, the Examiner contends that claim 33, which recites that “said outlier protein can elicit an immune response,” does not clearly limit the method of the independent claim.

The claims have been extensively reviewed and amended to address all of these issues, which relate entirely to claim language.

Withdrawal of these rejections is requested.

III. Conclusion

In the interest of compact prosecution, and given that this application has now been pending for 51/2 years, the Examiner is kindly requested to contact the undersigned to efficiently address any issues that might remain, and which the Examiner believes can be appropriately resolved in this manner.

Amendment Under 37 C.F.R. § 1.111
Application No. 09/820,843

Attorney docket: Q63915

In view of the above, it is strongly believed that the present application is in condition for allowance, and such actions are hereby solicited.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

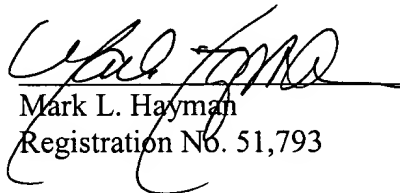
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